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This Standard Evaluation Procedure (SEP) describes the procedures used by EPA to evaluate residue studies on seed treatments, crops grown for seed, post-harvest fumigation, and other post-harvest treatments. First, the classification of seed treatments and treatments of crops grown for seed as non-food or food use is examined. Requirements for a treatment to be classified as a non-food use are described and include the availability of a radiotracer study showing no uptake of radioactivity to aerial portions or edible root portion of the growing crop, the seed itself not being a raw agricultural commodity, no likelihood that there will be residues in crops grown from treated seeds, and subsequent to treatment, all parts of the crop must be unfit for human or livestock consumption. Second, post-harvest fumigation of crops and processed foods and feeds is examined in detail. A description of important parameters which should be considered in evaluation of these studies is provided, as well as an Appendix which lists these considerations and others. Finally, post-harvest treatment (except fumigation) of crops and processed foods and feeds is discussed. Major treatments discussed include those made by dips, drenches, mechanical foamers, spray and brush applications and washes.

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PB88-244454

HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

SPECIALTY APPLICATIONS

(I) CLASSIFICATION OF SEED TREATMENTS AND TREATMENT OF CROPS GROWN FOR SEED USE ONLY AS NONFOOD OR FOOD USES

(II) MAGNITUDE OF THE RESIDUE: POSTHARVEST FUMIGATION OF CROPS AND PROCESSED FOODS AND FEEDS

(III) MAGNITUDE OF THE RESIDUE: POSTHARVEST TREATMENT (EXCEPT FUMIGATION) OF CROPS AND PROCESSED FOODS AND FEEDS

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STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

Anne L. Barton, Acting Director
Hazard Evaluation Division

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HAZARD EVALUATION DIVISION

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SPECIALTY APPLICATIONS

(I) CLASSIFICATION OF SEED TREATMENTS AND TREATMENT OF CROPS GROWN FOR SEED USE ONLY AS NONFOOD OR FOOD USES

SPECIALTY APPLICATIONS

(I) CLASSIFICATION OF SEED TREATMENTS AND TREATMENT OF CROPS GROWN FOR SEED USE ONLY AS NONFOOD OR FOOD USES

I. INTRODUCTION

Purpose

This Standard Evaluation Procedure is designed to aid Residue Chemistry Branch (RCB) reviewers in evaluating whether seed treatments and treatment of crops grown for seed use only should be categorized as nonfood or food uses.

II. SEED TREATMENTS

This use includes cases where seed is treated either by the seed company (and dyed according to the Seed Act) or by the farmer (planting box or hopper treatments).

For a seed treatment to be considered a nonfood use, the following is required:

- Data from a radiotracer study demonstrating no uptake of activity to the aerial portion and edible (for both human and livestock consumption) root portion of the growing crop.

If activity from a radiotracer study occurs in the aerial and edible root portions of the crop or if no study is available, seed treatments are considered to be food uses, requiring tolerances and appropriate residue data in support of the tolerances. In most cases where a tolerance is required, the tolerance normally would be set at the limit of detection of the analytical method.

III. TREATMENT OF CROPS GROWN FOR SEED ONLY

Three requirements must be met in order for uses on crops grown for seed only to be considered nonfood uses. They are listed below.

- The seed itself is <u>not</u> a raw agricultural commodity (RAC).

  Examples of crops where the seed itself is an RAC are corn, sorghum, soybeans, small grains, and sunflowers. For these crops, seeds from treated crops could not be distinguished from those from untreated crops and could be diverted to human and animal consumption. Thus, cases where the seed itself is an RAC are considered to be food uses. To determine whether the seed itself is an

RAC, the reviewer should consult Table II in the Residue Chemistry Guidelines.

o There is no likelihood of residues in crops grown from harvested seed.

Factors affecting this requirement include the systemicity and the persistence of the pesticide, the expected level of residues in/on the harvested seed, and the weight of the seed in relation to that of the second generation crop.

o Subsequent to treatment, all parts of the crop are not fit for human consumption nor fed to livestock.

The requirement that the crop is not fed to livestock can be met when no parts of this crop are livestock feed items or palatable to livestock subsequent to treatment, or if a reasonable restriction can be imposed against feeding the treated crop to livestock.

Examples of uses where the crop is not fit for human consumption following treatment nor fed to livestock are desiccant use on okra and postbloom applications to leafy vegetables and Brassica (cole) leafy vegetables. Since okra, following desiccation, and leafy and Brassica (cole) leafy vegetables, following the bloom stage of development, are not fit for human consumption and since these crops are not livestock feed items, desiccant use on okra and postbloom applications to leafy and Brassica (cole) leafy vegetables would be considered nonfood uses, provide there is no likelihood of residues in/on the harvested seed. A similar example is use on table beet and carrot stecklings grown for seed. Stecklings are plants of biennial root crops which are dug and stored over winter and then replanted the next season for seed production. A second season use on table beet and carrot stecklings grown for seed production would be considered a nonfood use because beets and carrots are not livestock feed items and because 2 to 3 weeks after replanting the stecklings a flower stalk is produced, at which time the root becomes fibrous and undesirable for human consumption.

Generally, alfalfa and clover grown for seed cannot be considered nonfood uses because of the economic importance of alfalfa and clover hay. Subsequent cuttings for hay would be taken regardless of label restrictions. In addition, use on alfalfa grown for seed only cannot be considered a nonfood use because of the increasing importance of alfalfa sprouts as a human food item. However, desiccant use on clover grown for

seed can be a nonfood use because desiccation renders the hay unfit for consumption by livestock.

The above three requirements must be met in order for treatment of crops grown for seed only to be considered a nonfood use. When the above three requirements are not met, the use is considered to be a food use, requiring tolerances and the appropriate residue data in support of the tolerances. However, for the purposes of a special local need [24(c)] registration, exceptions may be made on a case-by-case basis if only the third requirement is not strictly met. Compelling reasons must be provided by the registrant to consider the treatment a nonfood use. Often the unique culture for the production of a seed crop, as compared to the culture for the production of a food or feed crop, results in a crop which is inedible, matures at a different time than the normal food or feed crop, and/or is not commercially viable as a food or feed crop. The 24(c) applications for these uses should include the rationale as to why the proposed treatment would be a nonfood use, as well as practical assurances by State officials that the crop would not be diverted to food or feed. Exceptions will not be made if the first two requirements are not met; i.e., exceptions will not be made if the seed in question is an RAC and if there is a likelihood of residues in crops grown from harvested seed. Generally, exceptions will also not be made for alfalfa and clover because of the economic importance of alfalfa and clover hay.

IV. REVIEWER AID MATERIALS

In addition to the RCB file for nonfood uses, the reviewer should consult Appendix 2 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.

HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

SPECIALTY APPLICATIONS

(II) MAGNITUDE OF THE RESIDUE: POSTHARVEST FUMIGATION OF CROPS AND PROCESSED FOODS AND FEEDS

SPECIALTY APPLICATIONS
(II) MAGNITUDE OF THE RESIDUE: POSTHARVEST FUMIGATION OF CROPS AND PROCESSED FOOD AND FEEDS

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid RCB reviewers in their evaluations of postharvest fumigation trial studies submitted by petitioners/registrants. It is meant to be used as a supplement to the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials (published in FY '85).

Fumigation may be defined as the act of releasing and dispersing a toxic chemical so that it reaches the organism wholly or primarily in the gaseous or vapor state. In the case of postharvest fumigation, both RACs and processed foods and feeds may be treated.

This particular Standard Evaluation Procedure addresses the magnitude of the first-generation residue in crop RACs and processed food and feed commodities resulting from postharvest fumigation of these commodities.

B. Objective of the Postharvest Fumigation Trial

Postharvest fumigation trial studies should answer the following question: What is the maximum level of "total toxic residue"[1/] that will likely result in or on the RAC or in or on the processed food or feed commodity as a result of the postharvest fumigation of these commodities with the pesticide formulated product according to the proposed label directions for use?

II. INFORMATION TO BE SUPPLIED

The petitioner/registrant's report on postharvest fumigation trials on RACs or processed food or feed commodities should include all information necessary to provide a complete and accurate description of the commodities (including bulk storage, container information) and fumigation trial treatments and procedures; rate of application; fumigation chamber (including construction materials, geometry, and air tightness); temperature; pressure; exposure time;

1/The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

aeration; sampling, handling, shipping, and storage of the RAC; storage stability validation of the test chemical (and metabolite(s) of special concern); residue analyses of samples for the "total toxic residue" (and for individual components of special concern); validation (recovery studies) of the residue analytical methodology; reporting of the data and statistical analyses; and quality control measures/precautions taken to ensure the fidelity of these operations.

A Guideline of specific information that should be included in the petitioner/registrant's report of postharvest fumigation trials is provided in the RCB Data Submission Guideline on the Magnitude of the Residue: Postharvest Fumigation Trials of Crops and Processed Foods and Feeds[2/] that complements this Standard Evaluation Procedure. Related information on Analytical Method(s) and Storage Stability are found in the Standard Evaluation Procedures and Data Submission Guidelines on those subject areas.[3/]

III. THE DATA EVALUATION PROCESS

A. Prepare A Summary

The initial step in the evaluation process of postharvest fumigation trials on an RAC is for the reviewer to carefully examine and summarize the information/data supplied by the petitioner/registrant in his submission to the Agency. Any statistical treatments of the data should be independently verified and the quality control precautions noted.

B. Identify Data Gaps

Using the Data Submission Guideline on Magnitude of the Residue: Postharvest Fumigation Trials as a guide (in conjunction with the related Guidelines on Analytical Method(s) and Storage Stability), the reviewer should then look for data gaps - omissions in the information supplied by the petitioner/registrant in his report. A judgment should be made as to which are considered significant enough to adversely affect the review process. Those data gaps significant enough to adversely affect the review process should be duly noted in the reviewer's report. Those so identified should be communicated back to the petitioner/registrant by the Product Manager for corrective action.

C. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness (vis-a-vis the intended use) and adequacy of the data/information

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2/To be developed.
3/Concurrently in preparation.

that has been supplied. The aforereferenced Data Submission Guidelines are a useful guide to the various parameters that need to be considered. Appendix 1 of this document discusses specific aspects of those parameters that warrant consideration.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available to him, such as the Residue Chemistry Guidelines (Subdivision O of the Pesticide Assessment Guidelines). A listing of some suggested source materials is located in Appendix 2 to this document.

Any perceived deficiencies in the data/information supplied should be identified and explained, with a statement as to what steps should be taken to resolve the deficiencies, so that this information can be relayed back to the petitioner/registrant by the Product Manager for appropriate action.

Note: Other aspects of the Magnitude of the Residue, such as processed food/feed and meat/milk/poultry/eggs considerations are to be addressed in separate Standard Evaluation Procedure documents.[4/] Those considerations are applicable whenever an RAC (or parts thereof) or processed commodity may be utilized as an item of livestock or poultry feed, or whenever an RAC may be processed into feed items or human foods.

D. Determine the Need for Consultations with Other HED Branches

In considering the appropriateness and adequacy of the data/information that has been supplied, the data reviewer must also determine if consultations with other HED Branches are needed to reach that decision.

If so, the specific nature of the issue(s) in question should be clearly and succinctly stated and directed to the specific Branches whose input is sought.

E. Conclude if the Requested Action is Supportable

As the last step in the data evaluation process, the data reviewer makes a judgment as to whether the submitted data/information support the requested action (tolerance/registration) of the data submitter.

If the data are not supportive, possible alternative action(s) that may be taken by the petitioner/registrant are suggested.

4/Concurrently in preparation.

If deficiencies/omissions exist in the submitted data base, the reviewer may have to defer judgment until such time as appropriate corrective action has been taken by the petitioner/ registrant.

APPENDIX I

MAJOR POINTS TO CONSIDER IN EVALUATING RESIDUE DATA FROM POSTHARVEST FUMIGATION OF CROPS AND PROCESSED FOODS AND FEEDS

A. The Commodity

- Has the commodity been adequately identified in all the postharvest fumigation trials?

- Is the commodity an RAC or a processed food or feed?

- For RACs, are an adequate number of types and varieties represented and are the commercially important varieties represented?

- For RACs, is it clear what specific plant part(s) were harvested and then fumigated?

- Is it clear what specific processed commodity was treated (e.g., hulls, meal, or flour)?

- Has the general condition (e.g., green/ripe, fresh/dry, etc.) of the commodity at time of fumigation been specified?

- Are there livestock or poultry feed items associated with the RAC or processed commodity? If so, are animal metabolism and feeding studies available? (Note: these concerns will be addressed in separate Standard Evaluation Procedures, concurrently in preparation.)

- Is the RAC normally processed into feed or food items? If so, have processing studies been conducted? (Ref. Footnote 1, page 4, this document.)

- Is supplementary information available for the pesticide in other reports by the petitioner/registrant on this commodity or related commodities that can be translated to support the data base, if needed?

- Are data for the pesticide under similar use conditions available on the representative RACs of the crop group to which this RAC belongs and, if so, should a crop group action be considered?

- Have there been experimental use permits/temporary tolerances, section 18 exemptions, or section 24(c) registrations for the commodity treated with this pesticide? Permanent tolerance petition requests?

- Are there Codex/FAO Monograph data available for this commodity or related commodities treated with this pesticide?

- Are there International Residue Limits (IRLs) established for use of this pesticide on this commodity and, if so, upon what use(s) were they established and what components of the residue are regulated? What would be required for harmonization with any such IRLs?

- Is there any other unpublished or published information known to us about this pesticide and commodity use that must be taken into consideration?

- Are all the important dates relative to the treating and sampling of the commodity reported?

B. The Pesticide

Refer to Appendix I, section (A)(2) in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials (published in FY '85).

C. The Fumigation Chamber, Application of the Pesticide, Aeration of the Commodity

- Do the fumigation trials reflect the intended use (proposed labeling) of the fumigant on the RAC or processed commodity?

- What type of fumigation chamber (e.g., grain elevator and flat storage, tarpaulin covering, shiphold, fumigation vault, vacuum chamber) was used for the trial?

- Are the size and geometry of the fumigation chamber reported?

- Were fumigation trials carried out in the fumigation chamber(s) listed on the proposed label?

- What is the overall airtightness of the fumigation chamber? This question is important because leakage reduces the concentration of pesticide released in the fumigation chamber.

- What materials (e.g., frame, metal, cement block, concrete, asphalt, plastic tarpaulins) were the fumigation chambers constructed of and were they porous or absorbent? Metal, asphalt, and concrete surfaces are less porous than wood and cement blocks. For instance, the porous nature of cement blocks allows leakage.

- Were chamber surfaces covered with a material which reduces leakage (e.g., covering the chamber surfaces with asphalt

paper or plastic tarpaulins [often not practical on large operations] or paint)?

- What measures were taken to seal the fumigation chamber? Were all vents, chimneys, etc. closed or sealed with polyethylene bags? Were doors, windows, cracks, etc. sealed with masking tape?

- What were the wind conditions outside the fumigation chamber? Were there any drafts inside the chamber? Drafts can cause escape of the fumigant from the chamber.

- Was there a large temperature differential between the space inside the chamber and the environment outside the chamber, aiding escape of the fumigant?

- What was the relative size of the fumigation chamber as compared to the commodity load? The smaller the relative size of the commodity load, the higher the expected residues because less material is available to absorb the fumigant.

- How were the commodities arranged during the fumigation? What size were the stacks of commodities? Can the fumigant penetrate to the middle of the stack of a given commodity?

- What kind of material were the containers holding the commodities made of? Were the containers permeable (e.g., untreated kraft paper, burlap, containers of slatted wood)? If not, were the packages or containers opened? Examples of relatively nonpermeable containers are cellophane, plastic, waxed, laminated, polyethylene, waterproof paper, and tight wooden packing cases. Nonpermeable containers hinder both absorption of the chemical during the fumigation period and desorption of the chemical during the aeration period. What is the affinity of the container material for the fumigant? During aeration, the container can provide a secondary fumigation for the commodity if the container material has a high affinity for the fumigant.

- Was the commodity raised on pallets for fumigant circulation underneath the load? Was the air space above the load unobstructed for proper circulation?

- What kind of fumigant dispensing system was used and where were the discharge points? How was the fumigant volatilized? Were vaporizers used to hasten vaporization?

- What measures were taken to maximize gas circulation? Where were fumigant dispensers and circulating fans/blowers positioned?

- Was the application equipment and procedure similar to that used in commercial practice?

- Are dose rates reported in a manner (e.g., lb ai/1000 ft^3) that is consistent with normal practice and with the directions on the proposed labeling?

- Were temperature and pressure reported?

- Are the dates, number and timing of the application(s) given?

- What was the aeration time prior to sampling? For the purpose of worker safety, at the completion of the fumigation period, the fumigant will be evacuated from the sheltered area. Often, additional aeration is needed to prevent damage to the fumigated commodity or excessive chemical residues.

- Is the minimum aeration time specified on the proposed label and is it a practical one?

- How was the aeration carried out (removal of seals and covers, opening doors and windows, use of exhaust fans, use of air suction systems)? Was additional aeration performed outside the confines of the fumigation chamber? Was the aeration procedure similar to that on the proposed label and similar to that used in commercial practice?

- Are exaggerated rate data available?

- Are residue decline data (residue versus aeration time) available, including that past the proposed minimum aeration time specified on the label?

- Are data available on the aeration time necessary for residues to fall below tolerance? Below detectable levels?

- Are data available reflecting the maximum proposed use conditions (e.g., maximum dose rate(s), maximum exposure time, maximum temperature, airtight fumigation chambers, minimum aeration time, maximum number of treatments with the pesticide, minimum intervals between treatments)? If not, are the available data sufficient to allow for extrapolation?

- Are label restrictions needed?

- Were there a sufficient number of trials conducted on the commodities to support the requested action of the data submitter?

(Note: This is a judgment call and is influenced by the importance of the RAC or processed commodity, the range of conditions under which it is fumigated, the number of types of fumigation chambers listed on the proposed label, how closely the trials corresponded with the intended use pattern(s), whether exaggerated rate and residue decline data are available, whether a minor crop or minor use is involved, the data and established tolerances already available on related commodities treated with the pesticide under similar conditions of use, the nature of the requested action of the data submitter, and the general concern over the toxicity of the pesticide.)

D. Sampling, Conditions of Handling Between Storage and Analysis

- How soon after the fumigation period were samples taken? The time between the fumigation period and sampling is usually the aeration time, unless measures were taken to prevent desorption prior to the sampling of commodities.

- Is the sampling procedure described - i.e., the point of sampling, size (weight) of samples, and handling of samples?

- Where was the commodity sampled (e.g., top, bottom, or side; outer layer, center of stack; side or middle of chamber)?

- Given the treatment and aeration procedure, the description of the fumigation chamber, and properties of the fumigant, would residues be expected to be relatively low or high at a particular sampling point? For example, higher residues would be expected at lower sampling positions when the fumigant is more dense than air.

- How were samples stored prior to shipping, during shipping, and between shipping and analysis? WHat quality assurance measures were taken to ensure the fidelity of samples? Were samples immediately stored in packaging to ensure the integrity of the samples? If not, how were the samples stored? Given the volatile nature of fumigants, immediate proper packaging of samples is necessary.

- Was additional aeration performed after sampling? Should any of the time between sampling and analysis be considered as additional aeration time?

- What were the method(s) of packaging samples between sampling and analysis (container type(s)/size(s); sample sizes; temperature; labeling/dating/coding)?

- How long between sampling and shipping? How long were samples kept in storage? Were the dates of aeration, sampling, entry into storage before shipping, storage, and analysis given?

- Was any sample compositing or subsampling done at these stages? If so, were details given?

E. Storage Stability Validation Testing

Refer to the Standard Evaluation Procedure on Storage Stability Tests.[5/] In addition, given the volatile nature of the fumigants, emphasis may also be needed on studying the stability (degradation) of residues during the time between sampling and storage.

F. Residue Method(s) and Instrumentation

Refer to the Standard Evaluation Procedure on Analytical Methods.[5/]

G. Results of Postharvest Fumigation Trials on Crops and Processed Food and Feeds

Refer to Section E of Appendix 1 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[6/] However, an additional point should be made.

When evaluating postharvest residue data for the purpose of setting a tolerance, the reviewer must also take into consideration preharvest uses; the maximum "total toxic residue" expected from postharvest uses should be added to the maximum "total toxic residue" expected from preharvest uses.

H. Quality Control

Refer to Appendix 1 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[6/]

5/Concurrently in preparation.
6/Published in FY '85.

APPENDIX 2

REVIEWER AID MATERIALS

The following is a listing of useful aids for evaluating residue data from postharvest fumigation trials. This listing is a supplement to the reviewer aids listed in Appendix 2 of the Standard Evaluation Procedure for Crop Field Trials[7/] and Processed Food/Feed Studies.[8/]

1. Plant Protection and Quarantine Programs Treatment Manual, United Stated Department of Agriculture (1976).

2. Feeds and Feeding, Abridged, F.B. Morrison, Morrison Publishing Company, Clinton, IA (1961).

7/Published in FY '85.
8/Concurrently in preparation.

HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

SPECIALTY APPLICATIONS

(III) MAGNITUDE OF THE RESIDUE: POSTHARVEST TREATMENT (EXCEPT FUMIGATION) OF CROPS AND PROCESSED FOODS AND FEEDS

SPECIALTY APPLICATIONS
(III) MAGNITUDE OF THE RESIDUE: POSTHARVEST TREATMENT (EXCEPT FUMIGATION) OF CROPS AND PROCESSED FOODS AND FEEDS

I. INTRODUCTION

A. Purpose and Scope of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid RCB reviewers in their evaluations of trials for postharvest treatment of crops (except fumigations[9]) and processed foods and feeds submitted by petitioners/registrants. It is meant to be used as a supplement to the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[10]

This particular Standard Evaluation Procedure addresses the magnitude of the first-generation residue in foods and feeds (either RACs or processed commodities) resulting from postharvest treatments.

B. Background

Postharvest treatment of foods and feeds are applied by various means, including dips, drenches, mechanical foamers, and spray and brush applicators. Often, postharvest treatments involve the application of a wax coating. The application of wax coatings are accomplished by diluting the formulated pesticide with wax prior to treatment of the RAC, inclusion of wax in the pesticide formulation, or by application of the wax coating after treatment. Waxes may require warming prior to application (unless the ambient temperature is high, vegetable wax usually requires heating). Postharvest treatments may also include a detergent wash procedure, either prior to, during, or following treatment. Use directions for postharvest treatments sometimes call for an aqueous rinse following treatment. Since detergent is always rinsed off the crop, use directions calling for a detergent wash step during or following treatment necessitates a rinse step following treatment with a pesticide.

For dips, typically a forklift places bulk bins into a tank containing the treatment solution. A heavy lid is often placed over the tank to ensure that the commodities stay submerged. The bin is then removed and drained. In drench treatment, bulk bins are flooded, then allowed to drain. Excess solution is recovered and recycled for immediate reuse. Postharvest

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9/The magnitude of the residue from postharvest fumigation is addressed in a separate section of this Standard Evaluation Procedure.

10/Published in FY '85.

treatment by spray or brush applicators is generally accomplished as the commodities progress down a conveyor belt. For treatment using mechanical foamers, the treatment solution also contains a detergent. The treatment solution is "foamed" with a mechanical foamer and allowed to spill onto the commodity to be treated. Following treatment by foamer, the commodity is rinsed with water. Typically, dip and drench operations are performed outdoors, and spray, brush, and wax operations are located inside the packinghouse.

C. Objective of Trials for Postharvest Treatments

Trial studies of postharvest treatment of foods and feeds should answer the following question: what is the maximum level of "total toxic residue"[11/] that will likely result in or on the food or feed commodity as a result of the postharvest treatment(s) with the pesticide formulated product according to the proposed label directions for use.

II. INFORMATION TO BE SUPPLIED

The petitioner/registrant's report on trials for postharvest treatments on foods and feeds should include all information necessary to provide a complete and accurate description of trial treatments and procedures; sampling, handling, shipping, and storage of the commodity; storage stability validation of the test chemical (and metabolite[s] of special concern); residue analyses of samples for the "total toxic residue" (and for individual components of special concern); validation (recovery studies) of the residue analytical methodology; reporting of the data and statistical analyses; and, quality control measures/precautions taken to ensure the fidelity of these operations.

A Guideline of specific information that should be included in the petitioner/registrant's report of trials for postharvest treatments is provided in the Residue Chemistry Branch Data Submission Guideline on the Magnitude of the Residue: Postharvest Treatment (Except Fumigation) of Crops and Processed Foods and Feeds[12/] that complements this Standard Evaluation Procedure. Related information on Analytical Method(s) and Storage Stability are found in the Standard Evaluation Procedure and Data Submission Guidelines on those subject areas.[13/]

11/The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free and bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.
12/To be developed.
13/To be developed.

III. THE DATA EVALUATION PROCESS

A. Prepare A Summary

The initial step in the evaluation process for trials for postharvest treatments of foods and feeds is for the reviewer to carefully examine and summarize the information/data supplied by the petitioner/registrant in his submission to the Agency. Any statistical treatments of the data should be independently verified and the quality control precautions noted.

B. Identify Data Gaps

Using the Data Submission Guideline on Magnitude of the Residue: Postharvest Treatment (Except Fumigation) of Crops and Processed Foods and Feeds as a guide, in conjunction with the related Guidelines on Analytical Method(s) and Storage Stability, the reviewer should then look for data gaps - omissions in the information supplied by the petitioner/registrant in his report. A judgment should be made as to which are considered significant enough to adversely affect the review process. Those data gaps significant enough to adversely affect the review process should be duly noted in the reviewer's report. Those so identified should be communicated back to the petitioner/registrant by the Product Manager for corrective action.

C. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness (vis-a-vis the intended use) and adequacy of the data/information that has been supplied. The aforereferenced Data Submission Guidelines are a useful guide to the various parameters that need to be considered. Appendix 1 of this document discusses specific aspects of those parameters that warrant consideration.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available to him, such as the Residue Chemistry Guidelines (Subdivision O of the Pesticide Assessment Guidelines). A listing of some suggested source materials is located in Appendix 2 to this document.

Any perceived deficiencies in the data/information supplied should be identified and explained, with a statement as to what steps should be taken to resolve the deficiencies, so that this information can be relayed back to the petitioner/registrant by the Product Manager for appropriate action.

Note: As stated in Footnote 1, other aspects of the Magnitude of the Residue, such as second-generation residues in

processed food/feed/and meat/milk/poultry/eggs considerations are to be addressed in separate Standard Evaluation Procedure documents. Those considerations are applicable whenever a treated RAC (or parts thereof) or processed commodity may be utilized as an item of livestock or poultry feed, or whenever a treated RAC may be processed into feed items or human foods.

D. Determine the Need for Consultations with Other HED Branches

In considering the appropriateness and adequacy of the data/information that has been supplied, the data reviewer must also determine if consultations with other HED Branches are needed to reach that decision.

If so, the specific nature of the issue(s) in question should be clearly and succinctly stated and directed to the specific Branches whose input is sought.

E. Conclude if the Requested Action is Supportable

As the last step in the data evaluation process, the data reviewer makes a judgment as to whether the submitted data/information support the requested action (tolerance/ registration) of the data submitter.

If the data are not supportive, possible alternative action(s) that may be taken by the petitioner/registrant are suggested.

If deficiencies/omissions exist in the submitted data base, the reviewer may have to defer judgment until such time as appropriate corrective action has been taken by the petitioner/ registrant.

14/Concurrently in preparation.

APPENDIX I

MAJOR POINTS TO CONSIDER IN EVALUATING RESIDUE DATA FROM POSTHARVEST TREATMENT OF RAW AGRICULTURAL COMMODITIES

In addition to the concentration of the treatment solution, the magnitude of the residue from postharvest treatments is affected by many other factors. Some of these factors are: exposure time, method of application, temperature, type of diluent (e.g., water, wax), use of waxes, the particular wax, use of washed, chemical or detergent used for wash, use of rinses, length (volume) of rinse, brush speed, type of bristles, dump rate (bins dumped/hour), number of stops and starts on the line, measures taken to maintain solution strength, and the size, variety, maturity, and health of the fruit.

A. <u>The Commodity</u>

- Has the commodity been adequately identified in all postharvest treatment trials? Is the commodity an RAC or is it a processed commodity?

- Is it clear what specific plant part(s) were harvested and then treated?

- Are an adequate number of types and varieties represented and are the commercially important varieties represented? Has the general condition (e.g., maturity, health, size, etc.) of the commodity at time of treatment been specified?

- Are there livestock or poultry feed items associated with the commodity? If so, are animal metabolism and feeding studies available? (Note: these concerns will be addressed in separate Standard Evaluation Procedures, concurrently in preparation.)

- Is the commodity normally processed into feed or food items? If so, have processing studies been conducted? (Ref. Footnote 1, page 14, this document.)

- Is supplementary information available for the pesticide in other reports by the petitioner/registrant on this commodity or related commodities that can be translated to support the data base, if needed?

- Are data for the pesticide under similar use conditions available on the representative commodities of the crop grouping, and, if so, should a crop group action be considered?

- Are there any preharvest uses registered under review for this pesticide on the commodity in question? If preharvest uses are registered, what is (are) the tolerance(s)?

- Have there been experimental use permits/temporary tolerances, section 18 exemptions, or section 24(c) registrations for the commodity treated with this pesticide? Permanent tolerance petition requests?

- Are Codex/FAO Monograph data available for this commodity or related commodities treated with this pesticide?

- Are there International Residue Limits (IRLs) established for use of this pesticide on this commodity and, if so, upon what use(s) were they established and what components of the residue are regulated? What would be required for harmonization with any such IRLs?

- Is there any other unpublished or published information known to us about this pesticide and commodity use that must be taken into consideration?

- Are all the important dates relative to the treating and sampling of the commodity reported?

- Is this commodity considered a "minor crop" (i.e., limited acreage and low exposure)?

B. <u>The Pesticide</u>

For parameters concerning the pesticide, the reviewer should refer to Appendix I, section (A)(2) in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials. In addition, several other parameters should also be considered for postharvest treatments. They are listed below.

- Do the label directions indicate that the formulation is to be diluted with water or wax prior to treatment, or is wax already contained in the formulation as a carrier (diluent) for the pesticide?

- Does the label give directions for dilution of the formulation (e.g., x parts formulation to y parts diluent; x ounces formulation to y gallons diluent) to the treatment concentration?

- If label directions recommend the addition of a specific wax to the formulation, are the constituents of the recommended wax exempt from the requirements of a tolerance under 40 CFR 180.1001 or generally recognized as safe under 21 CFR 184?

- Do the directions for use recommend the addition of any detergents to be added to the formulation? If a specific detergent or any other additives are to added, is the detergent (additive) exempt from the requirements of a tolerance under 40 CFR 180.1001 or generally recognized as safe under 21 CFR 184?

- Are there any restrictions for this use on the proposed label? Are any label restrictions needed? Are the restrictions practical? A restriction against postharvest treatments if the RAC was treated prior to harvest is not practical since the prior treatment history of the crop is generally not known at the packinghouse.

C. Application of the Pesticide

- Do the the trials for postharvest treatments of foods and feeds reflect the intended use (proposed labeling)?

  Residue data should include that from trials reflecting the maximum concentration of the treatment solution and maximum exposure time and/or quantity pesticide applied per unit weight commodity, as specified on the proposed label. In the case of postharvest dips, the specification of a maximum exposure time is a practical label restriction and should be included on the label. For other methods of application, label directions restricting the maximum exposure time and/or quantity pesticide per unit weight commodity may not be practical and, often, restrictions regarding the maximum exposure of the commodity with the treatment solution is not specified on the label. Thus, the reviewer may need to make a judgment as to whether the submitted studies include trials reflecting maximum exposure with the treatment solution.

  Trials should be carried out using the diluent (e.g., water, wax) specified on the label. When the use of a particular wax coating is indicated on the label, residue data should include trials using the particular wax when the wax is applied by diluting the pesticide formulation with the wax. Generally, though, labels only indicate the use of "wax." Then, trials using different waxes are preferable to those using the same wax.

  Trials should reflect the methods of application (e.g., dips, drenches, mechanical foamers, spray applicators, brush applicators, wax applicators) specified on the label, as commercially practiced. Trials should also reflect the proposed use for application of wax coatings, detergent washes, and rinses with respect to number, method, timing (in relation to other steps in the procedure), and volume (or concentration, where applicable), particularly when the

proposed use for waxes, washes, and rinses is expected to have an effect on the magnitude of the residue. For example, the number and volume of rinses following pesticide application will have a critical effect on the magnitude of the residue. Although label directions usually do not specify a minimum volume of rinse water, the volume of rinse water used for the trials should reflect the extremes of the dictates of commercial practice.

Residue data for trials carried out at temperatures reflecting commercial practice storage conditions should be submitted. Residue data for storage at more than one temperature may be required. Variations in temperature for commercial postharvest treatments can depend on weather, climate control (or lack thereof) in the packinghouse, the particular requirements of the commodity, and the temperature requirements of the wax.

- Were there a sufficient number of trials conducted on the commodities to support the requested action of the data submitter?

  (Note: This is a judgment call and is influenced by the importance of the commodity, the range of conditions under which it is treated, the number of postharvest methods of application listed on the proposed label, the number of diluents, waxes, and other additives listed on the proposed label, how closely the trials corresponded with the intended use pattern(s), whether trials from exaggerated treatments are available, whether a minor crop or minor use is involved, the data and established tolerances already available on related commodities treated with the pesticide under similar conditions of use, the nature of the requested action of the data submitter, and the general concern over the toxicity of the pesticide.)

D. Sampling and Storage of Samples

Refer to Appendix 1 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[15/]

E. Storage Stability Validation Testing

Refer to the Standard Evaluation Procedure on Storage Stability Tests.

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F. Analytical Methods

Refer to the Standard Evaluation Procedure for Analytical Methods. However, one additional point should be made.

For RACs having skins or shells, registrants occasionally analyze only the skin or shell of RACs treated postharvest, and then calculate the residue on the basis of the whole fruit. Residue data for the skin or shell only is acceptable only when additional residue data are available for the particular RAC demonstrating that detectable residues are found in the skin and detectable residues are not found in the flesh. However, since tolerances are set on the basis of the whole fruit, analysis of the whole fruit is preferable to analysis of the skin only.

G. Results of Postharvest Treatments of RACs

Refer to Section E of Appendix 1 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[16/] However, an additional point should be made.

When evaluating postharvest residue data for the purpose of setting a tolerance, the reviewer must also take into consideration preharvest uses; the maximum "total toxic residue" expected from postharvest uses should be added to the maximum "total toxic residue" expected from preharvest uses.

H. Quality Control

Refer to Appendix 1 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[17/]

16/Published in FY '85.
17/Published in FY '85.

APPENDIX 2

REVIEWER AID MATERIALS

Refer to Appendix 2 in the Standard Evaluation Procedure for Magnitude of the Residue: Crop Field Trials.[18/]

18/Published in FY '85.